REMARKS

Claims 56-58 remain pending in this application for consideration. Claims 1-55 have been previously cancelled. Submitted herewith is a replacement Abstract having fewer than 150 words, titled "Replacement Abstract". Also submitted herewith is a Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection, along with the requisite fee. Further submitted herewith is a petition for a one-month extension of time in which to file this response, along with the requisite fee.

Specification

As requested by the examiner, the Abstract of the Specification has been amended so as not to exceed 150 words. Submitted herewith on a page titled "Replacement Abstract", Thus, Applicant believes that the examiner's objection to the Abstract has been overcome.

Double Patenting

The examiner provisionally rejected claims 56-58 of the present application under the doctrine of obviousness-type double patenting as being unpatentable over several claims in copending application Serial No. 10/683,506. Enclosed herewith is a Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection Over a Pending Reference Application, along with the requisite fee. Applicant believes that this disclaimer overcomes the examiner's rejection of claims 56-58 on the basis of obviousness-type double patenting.

Rejections Under 35 C.F.R. § 103(a)

In the Office Action of December 16, 2004, the examiner has maintained her rejection of claims 56 and 57 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,646,046 to *Fischer* et al. ("*Fischer*") in view of U.S. Patent No. 5,532,941 to *Lin* ("*Lin*"), in further view of U.S. Patent No. 6,507,765 to *Hopkins* et al. ("*Hopkins*"). The examiner also rejected claim 58 under 35 U.S.C. § 103(a) as being unpatentable over *Lin* view of *Fischer*. Applicant respectfully traverses the rejections for the following reasons:

Fischer

Fischer is directed to a fully automated analyzer and method for testing blood samples in a clinical laboratory (Abstract, lines 1-3). As described in *Fischer*, the analyzer is adapted to itself automatically handle a high throughput of samples (Col. 4, lines3-6). The analyzer of *Fischer* itself collects data and analyzes the sample-to-sample variability of collected data on that single analyzer (see *Fischer*, column 19, lines 61-67). There is no output of the variability analysis performed by the analyzer in *Fischer*.

Lin

Lin discloses an external quality control system for monitoring the performance of a large group of laboratory instruments located at geographically distributed laboratories. As shown in FIG. 1 of *Lin*, the system comprises a plurality of laboratories 21a-21n having laboratory instruments 22a-22n of the type to be monitored in a quality control system. The laboratory instruments 22a-22n include data storage and communication modules 24a-24n for capturing control data and reporting such control data over a plurality of communication links 31a-31n to a central quality control site 40.

The central quality control site 40 includes a communication interface 41 for receiving the control data from the laboratory instruments 22a-22n. A control data storage module 44 stores the control data received from the laboratory instruments 22a-22n, and a target data storage module 46 stores the control data received from a "golden peer group." The "golden peer group" is comprised of a subset of the laboratory instruments 22a-22n that have proven to be operating at a high level of quality as determined by a peer group selector 52. The target data storage module 46 also processes the "golden peer group" control data to determine targets against which all of the laboratory instruments 22a-22n are compared.

The central quality control site 40 also includes a comparator 47 that compares the control data stored in the control data storage module 44 against the "golden peer group" targets stored in the target data storage module 46 to thereby determine a concordance correlation coefficient (CCC) for each of the laboratory instruments 22a-22n. An evaluator 48 is also provided that rates the CCC for each of the laboratory instruments 22a-22n against the CCC distribution for the entire peer group and produces a CCC report 49 in accordance with such evaluation. The CCC report 49 may be electronically transmitted to each of the laboratories 21a-21n (note – not to the laboratory instruments) via communication links 31a-31n. Alternatively, a paper form of the CCC report 49 may be delivered to each of the laboratories 21a-21n by way of mail or the like.

Hopkins

Hopkins is directed to a computer integrated manufacturing control and information system. The system includes a plurality of processing machines which generate signals indicative of the parameters of the processing machines' operation (see Abstract). The

system of *Hopkins* provides real-time monitoring of parameters from the processing machines at a workstation or terminal (see col. 3, lines 1-5 and lines 20-25).

Claim 58

With respect to claim 58, the Examiner argues that it would have been obvious to one skilled in the art to combine the quality control evaluation system of *Lin* with the automatic analysis system of *Fischer* to arrive at the claimed invention. Applicant respectfully disagrees with the examiner's reasoning.

First, *Fischer* teaches a self-contained, automated, high-throughput analyzer, while *Lin* teaches an inter-laboratory performance monitoring system. The analyzer of *Fischer* operates independently, with no input or output of variability data. The system of *Lin* is a centralized analysis center which receives data from individual instruments, generates reports, and sends those reports to the laboratories at which the instruments are located. As disclosed, *Fischer* and *Lin* actually teach away from the Examiner's proposed combination. *Fischer* teaches a stand-alone analyzer while *Lin* teaches a networked system. One skilled in the art would not normally turn to two diametrically opposed technologies, as in *Fischer* and *Lin*, to come up with a solution to a problem neither reference even contemplated. As stated in MPEP § 2145, it is improper to combine references where the references teach away from their combination. Thus, since the cited references teach away from their combination, the rejection of claim 58 is improper, and should be withdrawn.

Furthermore, as stated in MPEP § 2143.01, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *Fischer* discloses only a stand-alone analyzer which performs its own, self-contained variability analysis. *Lin* discloses a central system in which

control data is not analyzed by an individual analyzer, but is processed at a central system. There is absolutely no teaching, suggestion, or disclosure in *Fischer* that the self-contained variability analysis data may be output or exported, nor is it even available externally. Similarly, there is absolutely no teaching, suggestion, or disclosure in *Lin* that an individual analyzer may itself perform control data analysis in lieu of sending data to the central system for processing. The combination suggested by the examiner is not present in either of the references, and in fact, would not even make sense. Since there is no suggestion in the cited prior art to make the suggested combination or modification, the rejection of claim 58 is unsupported by the art and should be withdrawn.

Even assuming, *arguendo*, the hypothetical combination of *Fischer* and *Lin,* that combination would not disclose the invention of claim 58 of the present application. Claim 58 of the present application claims a normalization system having: (1) one or more groups of laboratory instruments, (2) a normalization server in communication with the groups of instruments, (3) wherein the groups of instruments are in communication with the normalization server, (4) wherein the groups of instruments send data to the normalization server, and (5) wherein the normalization server outputs normalized outputs to the groups of laboratory instruments.

Fischer discloses a self-contained analyzer system which internally uses the variability analysis data it has itself generated. *Lin* discloses a quality control system in which data is collected and analyzed at a central system, with reports sent to the various laboratories. As shown in FIG. 8C and described in column 25, lines 13-19 of *Lin,* the final output taught in *Lin* is a report which is dispatched to the individual laboratories along with a cover letter. Unlike claim 58 of the present application, which requires sending the normalized outputs back to the

groups of laboratory instruments, the system of *Lin* simply compiles a statistical report that is sent to the laboratory facility (not to the instruments) for reading and interpretation by people at the lab. *Fischer* does not disclose sending normalized data to groups of laboratory instruments, *Lin* does not disclose sending normalized data to groups of laboratory instruments, and their combination does not disclose sending normalized data to groups of laboratory instruments. Thus, a combination of *Lin* and *Fischer* does not disclose sending normalized data to groups of laboratory instruments as required in claim 58 of the present application. For this additional reason, the examiner's rejection of claim 58 is improper, and should be withdrawn.

Claims 56 and 57

The examiner rejected claims 56 and 57 under 35 U.S.C. § 103(a) as being unpatentable over *Fischer* in view of *Lin,* in further view of *Hopkins*.

First, the *Hopkins* reference relied on by the examiner is not analogous art and is thus improperly used by the Examiner as the basis for rejection. As stated in §2141.01(a) of the MPEP, "[i]n order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned."

Claims 56 and 57 of the present application are directed to a method of modifying data from a group or groups of laboratory instruments. *Hopkins* is directed to a computer controlled manufacturing process system, i.e. an assembly/production line control system. A reference for a manufacturing process as disclosed in *Hopkins* is clearly not within the field of endeavor of one skilled in the art of the present application, which is directed to analysis of laboratory instruments.

In addition, the *Hopkins* reference is not pertinent to the problem at hand in the present application. The problem faced by present applicant, as stated in the specification, is that of facilitating the comparison of laboratory group results with peer group quality control results by mitigating differences in the instruments.

Hopkins, on the other hand, is directed to monitoring the flow of parts and assemblies through a manufacturing process. A workstation can be used to monitor parameters from various process machines (col. 8, lines 25-31) in order for an operator to pinpoint bottlenecks in the process, etc. One skilled in the art attempting to solve the problem faced by the present inventor, namely, facilitating the comparison of laboratory group results with peer group quality control results by mitigating differences in the instruments, would not even have considered *Hopkins*, which is directed to process flow control in a completely non-analogous field. Thus, *Hopkins* is not analogous art, and the rejection of claims 56 and 57 on this basis is unsupported by the art and should be withdrawn.

Second, as stated in MPEP § 2143.01, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *Hopkins* discloses a manufacturing process control system having real-time parameter monitoring. As discussed above, *Fischer* discloses only a stand-alone analyzer which performs its own, self-contained variability analysis. *Lin* discloses a central system in which control data is not analyzed by an individual analyzer, but is processed at a central system. There is absolutely no teaching, suggestion, or disclosure in *Fischer* that the self-contained variability analysis data may be output or exported, nor is it even available externally. Similarly, there is absolutely no teaching, suggestion, or disclosure in *Lin* that an individual analyzer may perform control data analysis itself instead of sending the data to the

central system. Likewise, there is absolutely no teaching, suggestion, or disclosure in *Hopkins* that the real-time parameter monitoring system could include a normalization curve made available over a network. The suggestion to combine made by the examiner in not present in any of the references, and in fact, would be non-sensical. Since there is no suggestion in the cited prior art to make the suggested combination or modification, the rejection of claims 56 and 57 is unsupported by the art and should be withdrawn.

Furthermore, even assuming that *Hopkins* were analogous art, and assuming that there were some suggestion to combine *Fischer*, *Lin,* and *Hopkins*, such a combination would not yield the invention claimed in claims 56 and 57 of the present application.

Claim 56 of the present application requires: obtaining data indicative of testing specimen outputs of the group of laboratory instruments, and normalizing the data according to a control group, generating a normalization curve for each laboratory instruments, and displaying the normalized data on a network. Claim 57 of the present application requires: obtaining testing specimen outputs from a first of two or more groups of laboratory instruments, obtaining testing specimen outputs from a second of the two or more groups of laboratory instruments; normalizing the testing specimen outputs from the first and second groups, and outputting at least one of the normalized first and second group outputs to a network.

Hopkins teaches only the monitoring of real-time parameters in the control of a manufacturing process (see col. 3, lines 1-6 and 21-25). Those real-time parameters may be monitored on a terminal or workstation (col. 5, lines 31-37 and col. 8, lines 26-32). However, there is no teaching, suggestion, or disclosure in *Hopkins* of analyzing or outputting any collected data to a network. The "network" of *Hopkins* is used simply to display, in real-time, the parameters associated with various manufacturing machines. The examiner cites *Hopkins* as

teaching that data may be output or displayed on a network. However, the data displayed in *Hopkins* is the real-time parameters being received from the manufacturing machines. There is no teaching, suggestion, or disclosure in *Hopkins* of centrally collecting data, creating a normalization curve (or any type of report) , and outputting that report on a network as required in claims 56 and 57 of the present application. Likewise, as discussed above with respect to claim 58, neither *Fischer* nor *Lin* make any such suggestion. Thus, even a hypothetical combination of *Fischer*, *Lin,* and *Hopkins* would not disclose a system in which a normalized data curve is output or displayed onto a network, as is required in claims 56 and 57 of the present application. For this additional reason, the examiner's rejection of claims 56 and 57 is unsupported by the art, and should be withdrawn.

In view of the foregoing remarks, it is respectfully submitted that all claims of the application are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be addressed in order to obtain allowance, he is invited to contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

Respectfully submitted,

By: _____

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